

An Open Source Clinical Research Infrastructure powered by caBIG

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Information Technology

Agenda

- Our Clinical Research Infrastructure (CRI) goal
- Implementations employing caBIG tools and standards
 - Participant
 - Registry
 - Calendar
 - Clinical Data Management
 - Lab values
 - Semantic Infrastructure and CDEs
- Next steps
- Conclusion and Questions

Our CRI goal

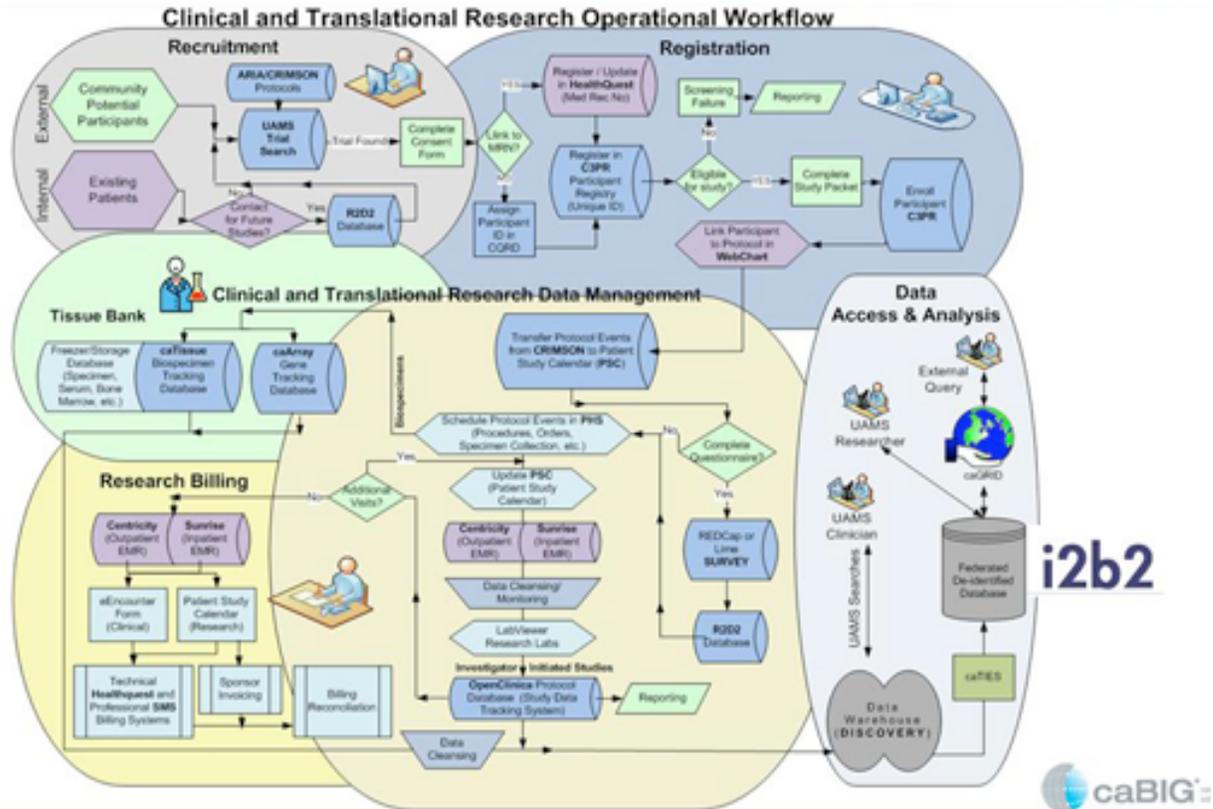
Where were we?

- No standards and tools in place,
- Many paper, MS Access, MS Excel based systems,
- Bioinformaticians and other researchers are/were spending 75-80% of their time to just locate data they need,
- It was a challenge to find who is in what study, what consent etc.
- No data integrity and quality measures in place

Our CRI goal-II

- We want to create an open and interoperable clinical research infrastructure
- Challenges;
 - *Must be a cost effective solution...*
 - *Very little additional funding (in house development will take too much time)*
 - *No Vendor(buying an app is not an option)*
 - *It should work.*
- *What is left?*
 - Collaborate and reuse standards and open source initiatives

Our TRI dream- a food web



The Catalyst...

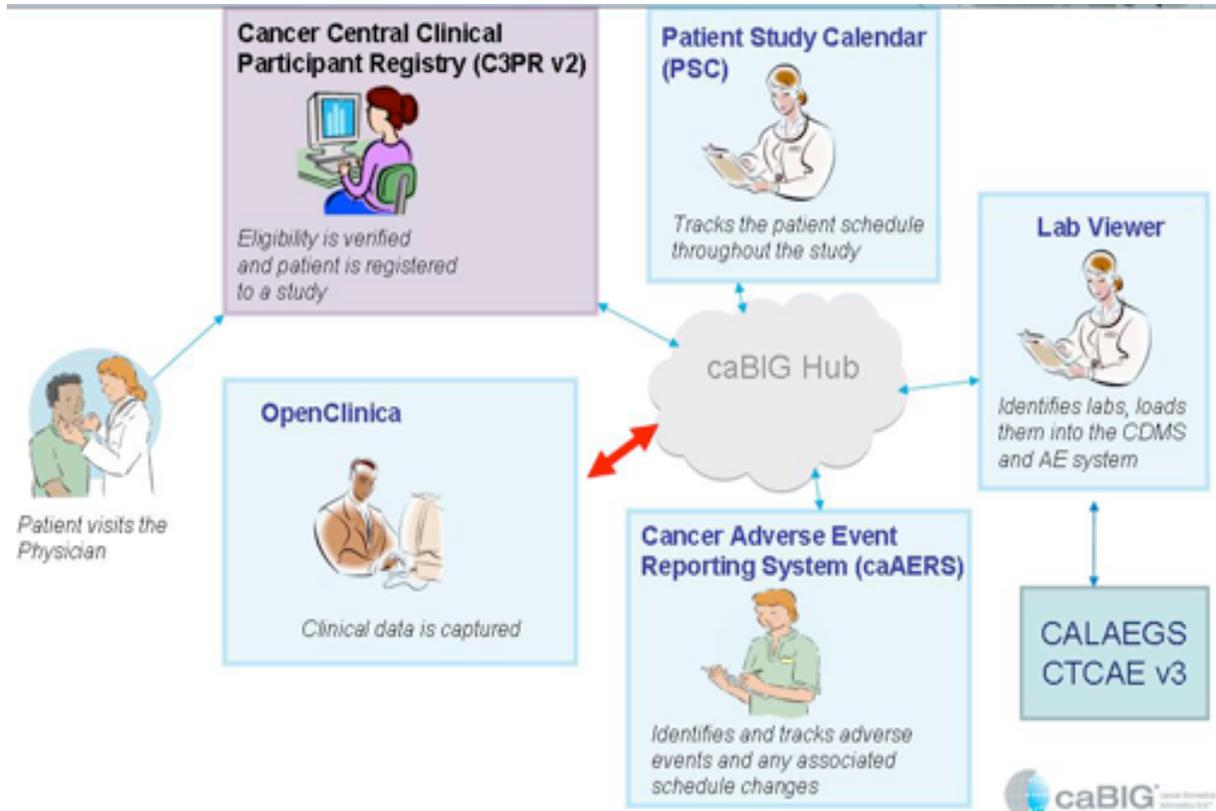
- Champions from the Winthrop P. Rockefeller Cancer Institute
- Some institutional funding
- Having a centralized IT and a dedicated team
- caBIG

Clinical Trials Management

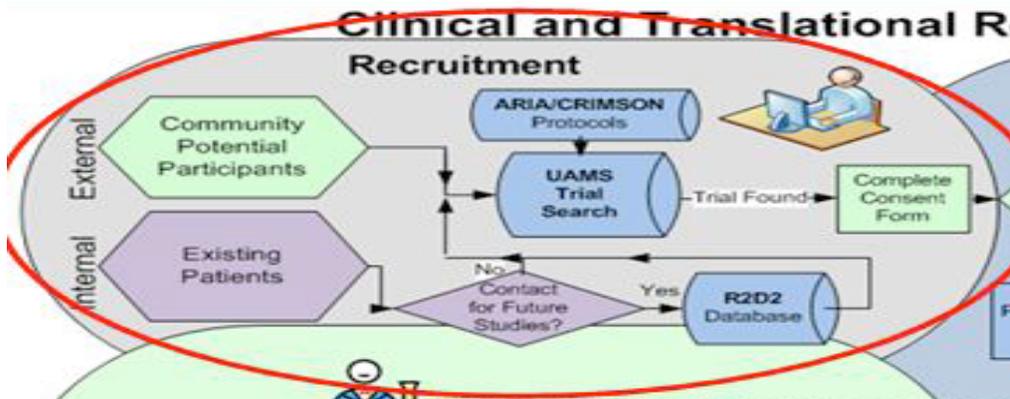
- Subject Management
 - The caBIG Suite
 - C3PR
- Calendar
 - Patient Study Calendar
- Adverse Event Reporting
 - CAAERS
- Lab Values
 - Labviewer
- Toxicity Grading
 - Other
 - CALAEGS
- Clinical Data Management

- OpenClinica

The Suite at UAMS



Our Dream: Recruitment



UAMS Trial Search- Recruitment

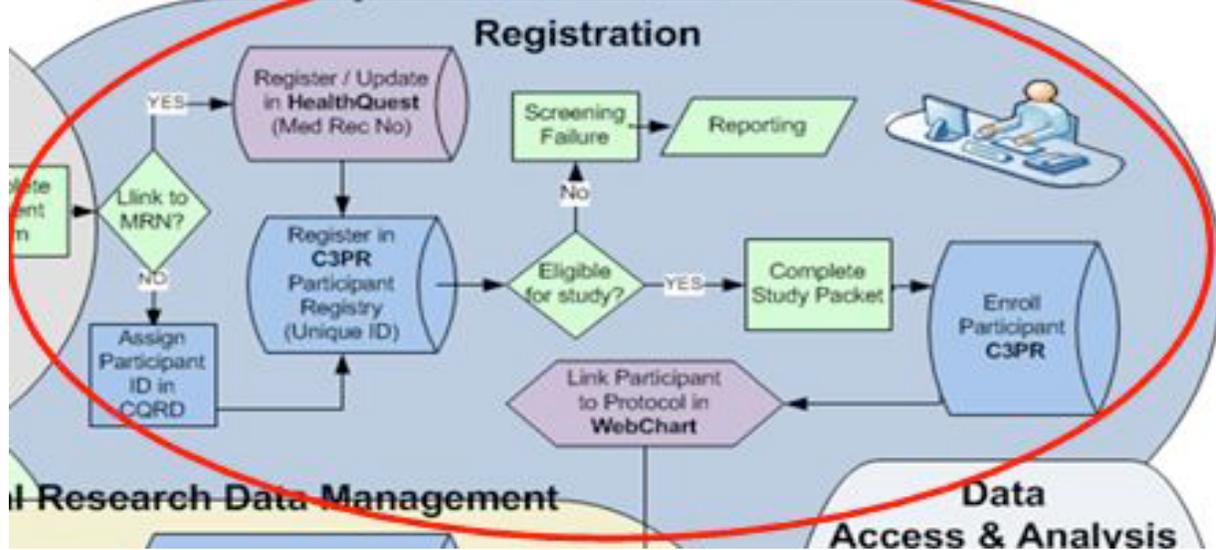
The screenshot displays the UAMS Clinical Trials Management website. The top navigation bar includes 'UAMS Clinical Trials Management' and a search bar. Below the navigation, there are two main content areas. The left area, titled 'Choose a disease site / subsite', lists various medical categories such as Adolescent Health, Aging, Bacterial and Fungal Diseases, and Cancers and other Neoplasms. The right area shows search results for a specific study. The study title is 'A Prospective, Non-Intervention, Observational Assessment of the Correlation between Circulating Biomarkers of Fungal Bioburden and Clinical Outcome in the Setting of Invasive Aspergillosis'. The IRB Number is 109709. The study is led by Principal Investigator Elias J Anasie and Contact Information Mark Mosby. The study summary states that it will take place at 15 hospitals in the United States, involving about 100 research participants, and that participants will be in the study for about 12 weeks. The study objectives and outcomes section mentions that the average of the z-scores of the time weighted averages of the serum measurements of (1,3)- β -D-glucan and galactomannan during the initial two weeks of anti-fungal therapy will be lower in patients with a successful clinical outcome compared to patients with a failed clinical outcome.

Research participant DB-Recruitment

- We are in process of developing an IRB protocol to create a system in which we can store
 - Potential participants
 - Apps we will use
 - re-contact allowed?
 - Collect Biospecimens
 - Questionnaires

Our Dream: Registration

Operational Workflow



caBIG's C3PR-

- Participant registry
 - It manages study, randomization, amendments etc.
 - Tracks subjects during screening, treatment, follow up
- We have added some additional functionality
 - Web service to import patient demographics
 - Integration with other systems
- There are 59 studies and 319 subjects in one of our instance

UAMS Event Tracker (ET)

UAMS Clinical Trials Management Welcome Umit Topaloglu!

Dashboard ARIA CRIMSON C3PR Study Calendar OpenClinica **ET** TrialSearch Reports User Guides Support Request

EventTracker Search by IRB or title

Protocol # 99075 Days to activation: 167

A Preliminary Study Utilizing a Flexible Endoscope for Pelvic Culdoscopy

[Basic Details](#) [Submissions](#) [Disease Sites](#)

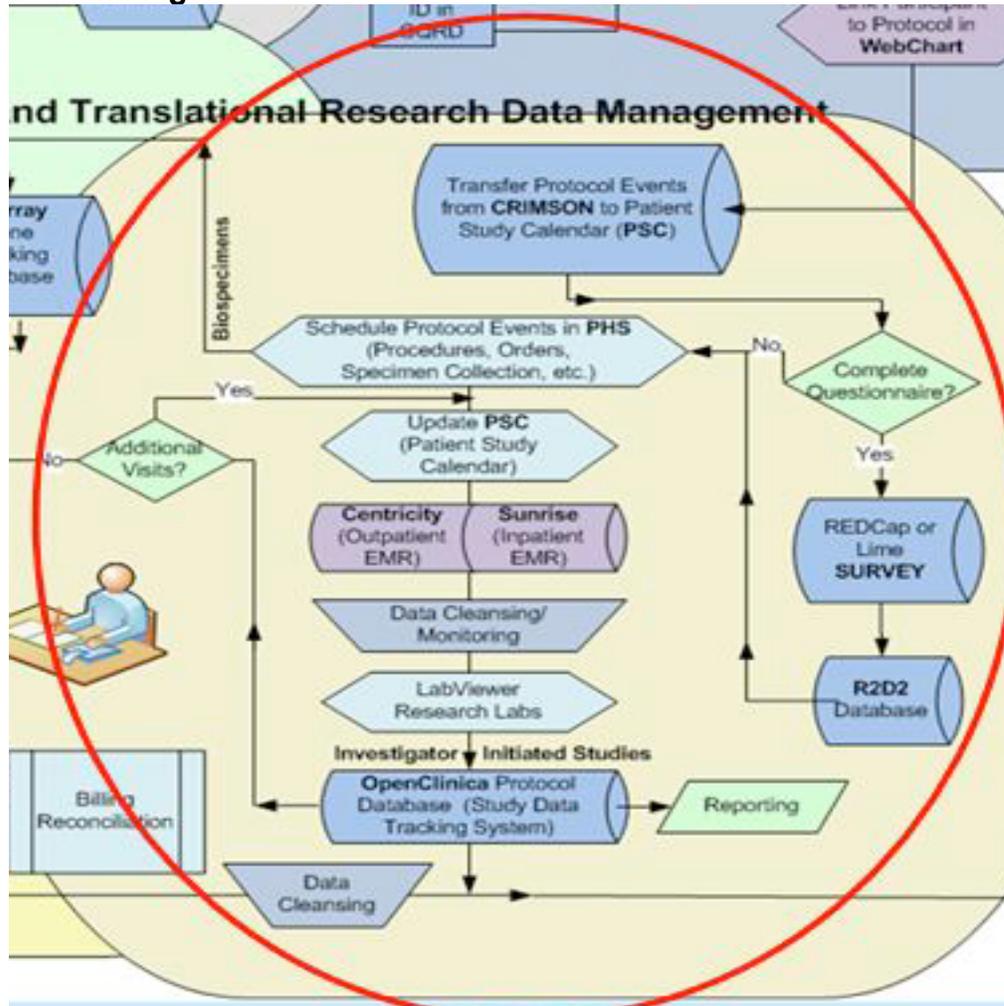
Activated (Open to Enrollment) on Feb. 18, 2008
[Change status](#) [View status history](#)

CRIMSON	IRB	Continuing Reviews
Created on Jan. 22, 2008	Submitted on Feb. 22, 2008	Last CR on Apr. 27, 2009
Completed on Feb. 21, 2008	Approved on Jun. 10, 2008	Next CR on Apr. 27, 2010

Protocol Committee Approvals

08/24/2009 Institutional Review Board:Sent	Days to approval: 20
09/13/2009 Institutional Review Board:Approved	

Data Management



caBIG's Patient Study Calendar

- Detailed study calendar
- It can manage;
 - all the study related activities
 - The same study structure with C3PR screening, treatment, follow up
 - Activities imported from our IRB system with "R", "C", "I" to represent what account the activity should be charged.

OpenClinica

Open Source Clinical Data Management

A Preliminary Study Utilizi... (99075) | Change Study/Site topalogluumit (Data Manager) | Log Out

OpenClinica®
Open Source for Clinical Research

Home | Subject Matrix | Notes & Discrepancies | Study Audit Log | Tasks ▾ Report Issue | Support | Study Subject Id

Alerts & Messages ▾

Instructions ▾

Info -

Study: A Preliminary Study Utilizing a Flexible Endoscope for Pelvic Culdoscopy

Start Date: 19-Mar-2009

End Date: N/A

PI: Alexander Burnett

Protocol Verification/IRB Approval Date: 06-Jul-2006

Welcome to A Preliminary Study Utilizing a Flexible Endoscope for Pelvic Culdoscopy

You are logged in as a Data Manager

0 Notes & Discrepancies Assigned to Me.

Site	Enrolled	Expected Enrollment	Percentage
A	2	20	10%

Study	Enrolled	Expected Enrollment	Percentage
A Preliminary Study Utilizing a Flexible Endoscope for Pelvic Culdoscopy	2	20	10%

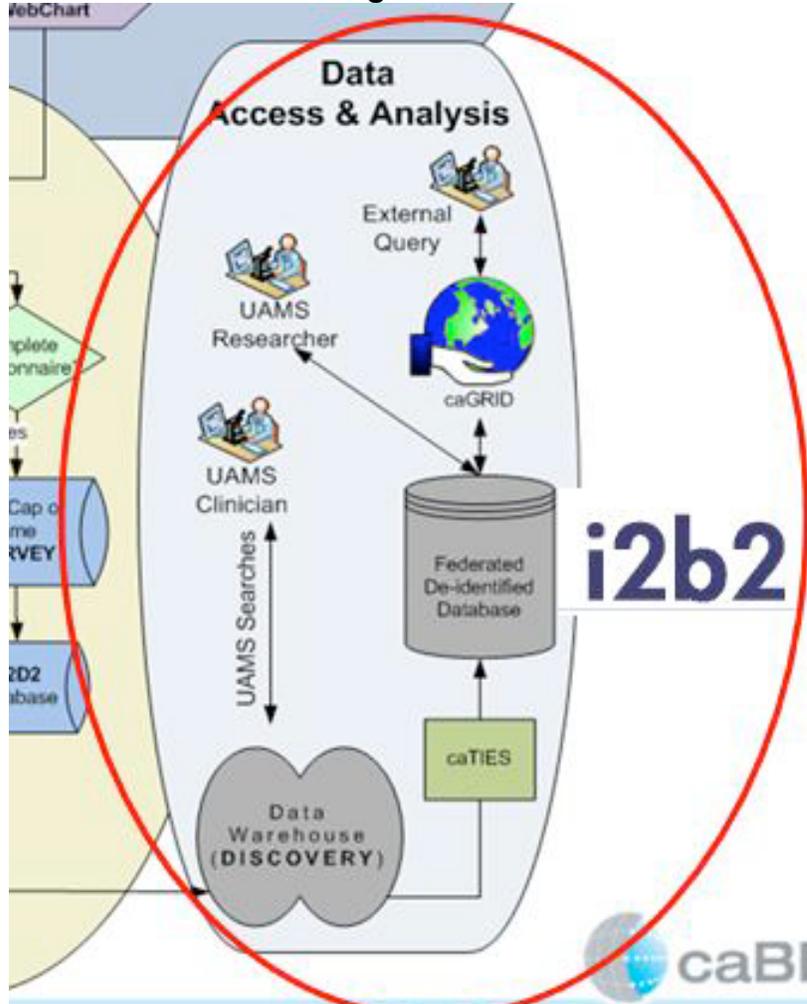
Event Status	# of Events	Percentage
scheduled	0	0%
data entry started	3	100%
completed	0	0%
signed	0	0%
locked	0	0%
skipped	0	0%
stopped	0	0%

Study Subject Status	# of Study Subjects	Percentage
available	2	100%
signed	0	0%
removed	0	0%

caBIG's Labviewer

- It is a tool to display lab results of a participant
- It can push the selected values to CDMS and/or CAAERS
- We have developed an interface to query CALAEGS for CTCAE V3 toxicity grading
 - It displays next to the lab result
- We are pilot testing

Our Dream: Data sharing and access



Data Access and Sharing-tech issues

- As we talk and trying to achieve semantic interoperability,
 - We need to identify terminologies and map to our data
 - Data sources should be identified
 - Common Data Elements (CDEs) are needed
 - Data warehouse may be a solution

Common Data Elements from caDSR

- It is an Cancer Institute mandate that all the data collections should be harmonized with CDEs
 - Case Report Forms (CRFs)
 - And Cancer Control Questionnaires
- It is a time consuming commitment.

- We have local curator in training to facilitate the process.

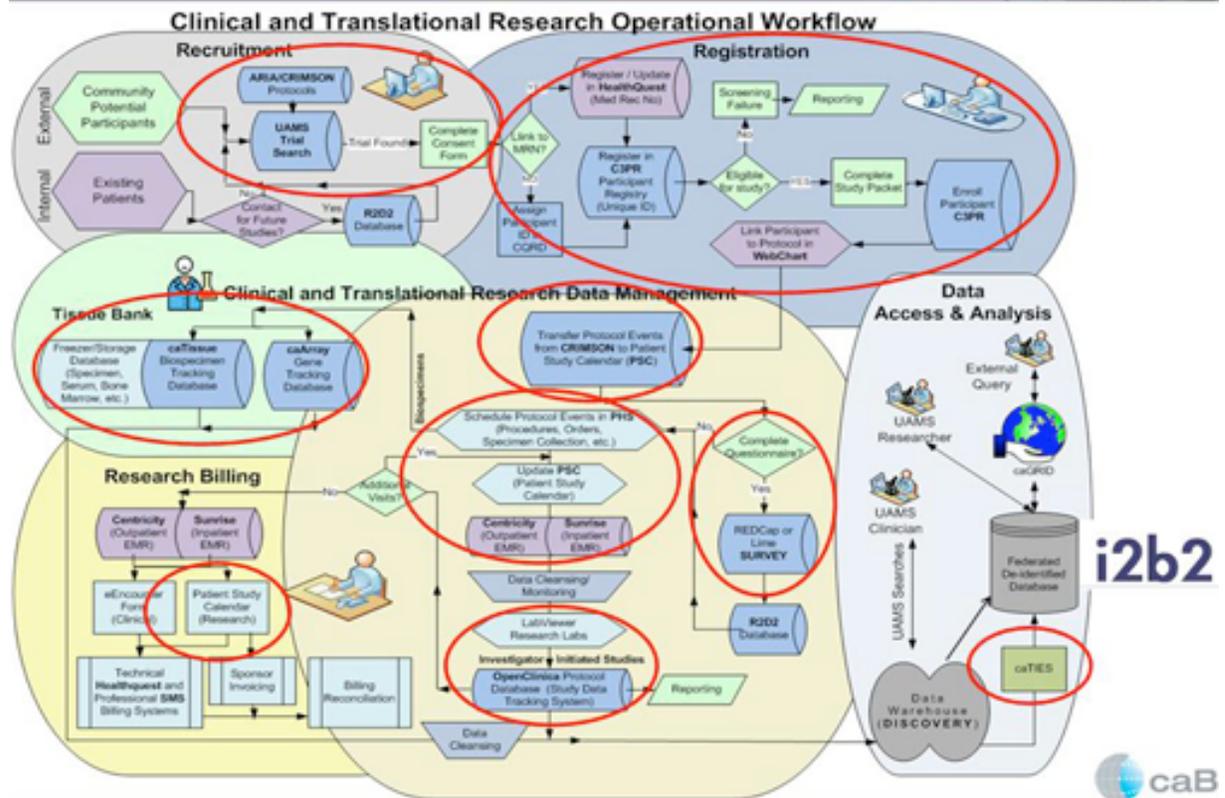
Creating a rules engine

- A request
 - “I want to set up an alert systems it should alert me when there is/are X adverse event with the severity of Y
- You can pull from adverse event or adverse effect CRFs.

What have we done so far?

- We are testing I2B2 with different cell options
 - Using LexEVS as terminology server
 - caTIES being NLP cell
- We have caBIG LexEVS in place with ICD9 and NCI thesaurus loaded.
 - Web service was implemented
- Trying to identify the use case openMDR for local metadata registry and reuse of models

Our Dream: where are we?



Future work

- Completing the remaining items in our vision picture
- Use of these tools to help in clinics during the clinical trial
 - Such as PSC
 - Sharing data on caGRID

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Research Portal with caTIES

- Ability to do web search on
 - deidentified free text reports, Deidentified demographics, Biospecimen search, Tumor registry

